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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,289	02/19/2004	Michael Edward Hilgers	LFS-5024	7605

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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

NT

Office Action Summary

Application No.

10/783,289

Applicant(s)

HILGERS ET AL.

Examiner

Matthew F. DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/04, 6/17/05, 6/09/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species A, Fig. 1a, 1B in the reply filed on 11/03/06 is acknowledged.
2. Claims 6, 7, 14, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species (the species dealing with the expanding portion), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/03/06.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 8-13, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas (USPN 6,332,871) in view of Vaslow (USPN 4,753,641).

Douglas discloses Douglas discloses a system and method for extracting bodily fluid from skin, the system comprising: a penetration member (16); a means for applying pressure (25) in an oscillating manner; and a means for varying pressure based on a measured characteristic of bodily fluid extracted from the skin (column 7, lines 3-7), as well as a method comprising penetrating a target site, applying pressure to the skin in an oscillating manner concentrically about a target site, and varying pressure based on

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a measured volume of bodily fluid extracted from the skin. Douglas further discloses a continuously Oscillating motion where the first time period of greater pressure and the second time period of lesser pressure as well as the operation of the dual alternating stimulation ring system shown in figure 19A will include time periods when one or both stimulations rings are completely removed from the skin. Douglas also teaches sampling interstitial fluid (column 4, lines 27-33) and for measuring glucose in ISF (column 2, line 64 - column 3, line 6 and column 7, lines 3-7), but Douglas fails to teach the specific limitations of the penetrating member.

Vaslow discloses a needle cannula with a distal end having a flexible feature (9, 10, 11) that has a first end, and a second end, wherein there is an arch between the first and second end (see figure 1-3).

Therefore, at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Douglas with the teachings of Vaslow because Vaslow discloses the added benefit of minimizing the penetration of the opposite wall of a vessel, as well as minimizing tearing and coring of the skin and tissue (Column 1, line 55 – Column 2, line 13 and col. 3, line 35 – col. 4, line 61).

5. Claims 1-5, 8-13, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas (USPN 6,332,871) in view of Kempf (USPN 4,585,446).

Douglas discloses Douglas discloses a system and method for extracting bodily fluid from skin, the system comprising: a penetration member (16); a means for applying pressure (25) in an oscillating manner; and a means for varying pressure based on a measured characteristic of bodily fluid extracted from the skin (column 7, lines 3-7), as

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well as a method comprising penetrating a target site, applying pressure to the skin in an oscillating manner concentrically about a target site, and varying pressure based on a measured volume of bodily fluid extracted from the skin. Douglas further discloses a continuously Oscillating motion where the first time period of greater pressure and the second time period of lesser pressure as well as the operation of the dual alternating stimulation ring system shown in figure 19A will include time periods when one or both stimulations rings are completely removed from the skin. Douglas also teaches sampling interstitial fluid (column 4, lines 27-33) and for measuring glucose in ISF (column 2, line 64 - column 3, line 6 and column 7, lines 3-7), but Douglas fails to teach the specific limitations of the penetrating member.

Kempf discloses a needle cannula with a distal end having a flexible feature (40a) that has a first end, and a second end, wherein there is an arch between the first and second end (see figure 6 and Column 4, line 1-7).

Therefore, at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Douglas with the teachings of Kempf because Kempf discloses the added benefit of minimizing tearing and coring of the skin and tissue (Column 4, line 45-47, Column 2, line 20-33).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-5, 8-13, 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/882,994 and 10/653,023 in view of Vaslow or Kempf.

The copending applications claim a method and apparatus that comprise a penetration member, and means for applying pressure (which is an oscillating ring), wherein the apparatus is used to sample ISF fluid. The copending applications don't claim the subject matter of a flexible feature on the penetration member. The previous cited art of Vaslow or Kempf teach the flexible feature on a needle cannula, as well as show motivation and a benefit of combining the two devices (see above 103 Rejections). Therefore, once the copending applications were modified in view of Vaslow or Kempf, the claims would be anticipated.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Matthew DeSanto
Art Unit 3763
January 22, 2007